

REMARKS

Entry of this Amendment is proper under 37 C.F.R. 1.116, because the Amendment places the application in condition for allowance for the reasons discussed herein; does not introduce any new claims; does not raise any new issue requiring further search and/or consideration because the amendments amplify issues previously discussed throughout prosecution, and places the application in better form for an appeal should an appeal be necessary.

Claims 1-12 and 16-31 are currently pending. Claims 8 and 12 are amended herein to remove the term "about". Thus, no new matter is submitted by way of the present Amendment. Applicants reserve the right to file at least one continuation or divisional application directed to any subject matter canceled by way of the present Amendment.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 8 and 12 stand rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite for the recitation of the term "about" in connection with the temperature range and the conductivity conditions. In order to expedite prosecution and without acquiescing in the rejection, claims 8 and 12 are amended herein to remove the term "about". Thus, this rejection is moot.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-12 and 16-31 stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the

inventors had possession of the claimed invention at the time the application was filed. More specifically, the phrase "wherein said method of inactivation is capable of preserving at least 80% of the infectious activity of the adenovirus preparation" is purportedly not supported by the specification. Applicants respectfully traverse.

Applicants draw the Examiner's attention to page 5, lines 11-18, of the specification, which recites "The examples which follow show that the action of 0.1 to 0.6% TNBP and of 1% to 2% Tween 80 for 4h at room temperature makes it possible to significantly reduce the quantity of enveloped viruses (reduction by a factor of at least 4 log units) while preserving the integrity of the adenoviral particles (*yield of at least 80%, or even greater than 100%*)" [emphasis added].

Further support may be found at Examples 4 and 5 of the present application, which illustrate that the claimed process is capable of preserving adenovirus infectivity providing a yield of infectious viral particles higher than 100%. Specifically, the table on the bottom of page 41 provides a summary of the titer in infectious units after each step of the process and recites yields over 100%. The last paragraph on page 42 recites "As a whole, the data show that the process of the invention allows the inactivation of enveloped viruses of a recombinant adenovirus preparation without harming their infectivity and with a total yield higher than 100%".

In light of the above remarks, Applicants submit that the specification provides clear support for "wherein said method of inactivation is capable of preserving at least 80% of the infectious activity of the adenovirus preparation" and that this phrase is not new matter.

CONCLUSION

From the foregoing, further and favorable consideration of the subject application on the merits is respectfully requested and such action is earnestly solicited.

If there are any questions concerning this Amendment, or the application in general, the Examiner is respectfully requested to telephone Applicant's undersigned representative so that prosecution may be expedited.

Respectfully submitted,

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